

**CHEMICALS UNDER CONSIDERATION FOR POSSIBLE LISTING AS
DEVELOPMENTAL AND REPRODUCTIVE TOXICANTS (DARTs) VIA THE
AUTHORITATIVE BODIES MECHANISM:
TRIBUTYLTIN METHACRYLATE, IDENTIFIED BY U.S. EPA**

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Reproductive and Cancer Hazard Assessment Section
Office of Environmental Health Hazard Assessment
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Tributyltin methacrylate may meet the criteria for listing under Proposition 65 via the authoritative bodies listing mechanism. The regulatory guidance for listing by this mechanism is set forth in Title 22, California Code of Regulations, Section 12306 (22 CCR 12306). For example, the regulations include provisions covering the criteria for evaluating the documentation and scientific findings by the authoritative body to determine whether listing under Proposition 65 is required.

The U.S. Environmental Protection Agency (U.S. EPA) has been identified as an authoritative body for purposes of Proposition 65 (22 CCR 12306(l)) and has identified tributyltin methacrylate as causing developmental or reproductive toxicity. This was done by that Agency in implementing its Toxic Release Inventory (TRI) program (*i.e.*, Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA)). On the basis of identifying chemicals which caused reproductive, developmental and/or other toxicities the U.S. EPA added a number of chemicals to the TRI list. The U.S. EPA published its toxicity findings in the *Federal Register* (**59**:1788-1859, 1994 and **59**:61432-61485, 1994). In proposing specific chemicals for addition to the TRI list, the Agency stated that a hazard assessment was performed for each candidate, "...in accordance with relevant EPA guidelines for each adverse human health or environmental effect..." (*Federal Register* **59**:1790).

OEHHA has found that tributyltin methacrylate has been "formally identified" as causing reproductive toxicity according to the regulations covering this issue (22 CCR 12306(d)) because the chemical has "been identified as causing ... reproductive toxicity by the authoritative body" (*i.e.*, U.S. EPA) "in a document that indicates that such identification is a final action" (*i.e.*, the TRI *Final Rule* (*Federal Register* **59**:61432)) and has "been included on a list of chemicals causing ... reproductive toxicity issued by the authoritative body" "and the document specifically and accurately identifies the chemical" and has been "published by the authoritative body in a publication, such as, but not limited to the federal register..."

OEHHA also finds that the criteria for "as causing reproductive toxicity" given in regulation (22 CCR 12306(g)) appear to have been satisfied for tributyltin methacrylate (CAS No. 2155-70-6). In making this evaluation, OEHHA relied upon the documents

and reports cited by U.S. EPA in making their finding that this chemical causes reproductive toxicity (for the developmental endpoint). OEHHA consulted additional sources of information on the specific studies cited by U.S. EPA. This was done only where necessary to affirm or clarify details of results and study design for studies cited by U.S. EPA.

The study cited by U.S. EPA in making findings with regard to the reproductive toxicity of tributyltin methacrylate is discussed below. The statement in bold reflects data and conclusions which appear to satisfy the criteria for sufficiency of evidence for reproductive toxicity in regulation (22 CCR 12306[g]). Where NOELs (no-observed-effect-level), LOELs (lowest-observed-effect-level), or LELs (lowest-effect-level) are included in the study descriptions below, they are quoted directly from the cited references.

Tributyltin methacrylate (CAS No. 2155-70-6)

Developmental toxicity was evidenced by reduced mean fetal weight and increased resorptions in rats.

The U.S. EPA (1994a and 1994b) concluded that "...there is sufficient evidence for listing tributyltin methacrylate on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(B) based on the available developmental toxicity data for this chemical."

Supporting documentation for the TRI listing (US EPA, 1993a) states, "Pregnant rats were given tributyltin methacrylate by gavage on days 6 to 19 of gestation. Mean fetal weight and maternal body weight gain were decreased at 18 mg/kg/day. Fetal resorptions were also significantly increased. The fetotoxic NOEL for this study was 9 mg/kg/d (27 [U.S. EPA 1981])."

With regard to the studies cited as supporting US EPA's action in adding a chemical to the EPCRA-TRI list, OEHHA has examined the original study (Bio/dynamics 1981) and finds that the evidence for DART effects appears to meet the criteria of 22 CCR 12306, and notes the following:

1. Adequacy of the experimental design:

Rat developmental toxicity study appears to be of adequate design for risk assessment purposes.

2. Route of administration:

Oral, gavage

3. The frequency and duration of exposure:

Once per day on each of gestation days 6-19.

4. The numbers of test animals:

Control group had 37 animals and three dose groups had 26 animals each.

5. The choice of species:

Rats are typically used in toxicity testing.

6. The choice of dosage levels:

0, 4, 9, or 18 mg/kg/day.

7. Maternal toxicity:

LEL = 18 mg/kg/day, NOEL = 9 mg/kg/day (based on significantly reduced maternal weight on gestation day 20 and weight gain for gestation days 6-20).

These values are identical to those determined for developmental toxicity, which are based on significantly reduced fetal weight and increased resorptions.

References

Bio/dynamics Inc. (1981) A teratology study in rats with tributyltin methacrylate. Final Report. Project No. 80-2487C. Submitted to M & J Chemical Company, Rahway NJ.

U.S. Environmental Protection Agency (US EPA, 1981). USEPA/OPP/HED. Memorandum from George W. Robinson to Richard Mountfort, RD, entitled "EPA File symbols 5204-AG and 5204-AU: bioMet 300 and Polyflo 2001A" dated (December 15, 1981) pages 8-10

U.S. Environmental Protection Agency (U.S. EPA, 1983). *Health Effects Test Guidelines; Teratogenicity Study*. Office of Toxic Substances, Office of Pesticides and Toxic Substances.

U.S. Environmental Protection Agency (U.S. EPA, 1993). *Support Document for the Addition of Chemicals from Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) Active Ingredients to EPCRA Section 313*. U.S. EPA Office of Pesticide Programs, Washington, DC.

U.S. Environmental Protection Agency (U.S. EPA, 1994a). Proposed Rule: Addition of Certain Chemicals; Toxic Chemical Release Reporting; Community Right to Know. *Federal Register* 59: 1788.

U.S. Environmental Protection Agency (U.S.EPA, 1994b). Final Rule: Addition of Certain Chemicals; Toxic Chemical Release Reporting; Community Right to Know. *Federal Register* 59(229): 61432.